REMARKS

This is in Response to the Office Action dated January 25, 2011. Claims 61-66 and 73-81 are currently pending in the Application and stand rejected. Applicants have amended claims 62, 66 and 80. Claim 62 has been amended for grammatical clarification. Claim 66 has been amended to provide appropriate antecedent basis. Support for the amendments to claim 80 is found in Example 12 of the Specification. No new matter was added.

Rejections over Stolle et al. and Van Donkersgoed

The Office Action rejected claims 61, 65-66, 73-76, 79 and 81 under 35 U.S.C. 103(a) as being unpatentable over Stolle et al. and Van Donkersgoed et al. The Office Action indicated that Stolle et al. teach a method for passively immunizing a mammal with heterologous antibody obtained from an immunized fowl which has been immunized against an antigenic substance. The Office Action alleged that Stolle et al. teach that antibody produced in one species can be used to neutralize the effects of the corresponding antigen in the other species and thus passive immunization occurs when an individual from one species receives immune protection from antibodies produced in an individual of another species. The Office Action alleged that the method (of Stolle et al.) teaches feeding a mammal a material having an enhanced antibody titer against an antigen obtained from the egg of fowl immunized against the antigen and administering to the mammal an immunologically effective amount of antibody. The Office Action indicated that any mammal can be treated and any antigen or combination of antigens can be employed including bacterial, viral, cellular or any other substance. The Office Action indicated that suitable antigens can include the species claimed in the present application and that the material fed to the mammal should be normal egg or may have an enhanced titer against the antigens and that the avian antibody has not lost its immunological effect.

The Office Action indicated that the method of Stolle et al teaches feeding the mammal a material having an enhanced antibody titer against an antigen obtained from the egg of fowl immunized against the antigen and administering to the mammal an immunologically effective amount of antibody and that Example 1 teaches using mixed bacterial strains for inoculation of the birds. The Office Action alleged that Stolle et al. teaches antigen selection sensitization of the fowl by primary immunization, testing of the eggs or serum, administration of boosters, testing antibody levels in the egg yolk and collecting eggs.

The Office Action indicated that the method is useful in humans and that the modes of administration include oral and parenteral administration. The Office Action alleged that parenteral administration involves piercing the skin or mucous membrane, while oral administration includes administration to the enteral/digestive tracts and respiratory tracts including bronchi, alveolar sacs and alveoli using liquids, such as inhalers, nebulizers, vaporizers and the like. The Office Action also alleged that oral administration can be used to treat diseases and that those of skill in the art can readily ascertain the amount of egg product or avian antibody to give to the mammal. The Office Action also indicated that Stolle et al teaches that the compositions can be used in the form of premixed food products or egg materials. The Office Action indicated that Stolle et al does not specifically recite which antigens can be used for decreasing respiratory illness in animals.

The Office Action indicated that Van Donkersgoed et al. teach respiratory disease in calves and vaccination protocols on passive immunity to *Pasteurella haemolytica* and *Haemophilus somnus* for combined vaccination and that higher antibody titers can be achieved in animals receiving passive administration of the combined vaccine.

The Office Action concluded that it would have been *prima facie* obvious to one of ordinary skill in the art to incorporate inoculation of antigens from a respiratory disease such as pneumonia as taught by Van Donkersgoed et al., to the method of decreasing animal respiratory illness as taught by Stolle et al. in order to provide more efficient passive immunization results. The Office Action also concluded that one of ordinary skill in the art would have a reasonable expectation of success. The Office Action also alleged that one of ordinary skill would have been motivated to make such a combination because Stolle et al. teaches the desire to produce the avian-derived immunoglobulins for pharmaceutical application in the treatment of disease while VanDonkersgoed et al teach the need to reduce sickness and death in animals. The Office Action further asserted that one having ordinary skill in the art would have been motivated to make such a combination because Stolle et al teach primary immunization with multiple specific antigens wherein all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function and combination would have yielded predictable results. The Office Action also alleged that it would have been prima facie obvious to combine the teachings of the cited art

to advantageously decrease animal respiratory illness and reduce the ability of the organisms to multiply after immunization while saving animals and preventing the expenses associated with animal sickness.

Applicants respectfully disagree. Applicants assert that the combination of Stolle et al. and VanDonkersgoed et al. does not teach the present invention and furthermore a person of ordinary skill in the art does not have a reasonable expectation of success that the invention as claimed would be successful. Applicants assert that Stolle et al. relates to passive immunization and provides a laundry list of bacteria and viruses that may be used as antigens. As asserted in the previously filed Response on November 9, 2010, there is no disclosure of spraying an egg mixture into the respiratory tract of an animal, let alone any detailed methodology related to this.

Applicants disagree with the Examiner's assertion that oral administration includes administration to the enteral/digestive tracts and respiratory tracts. Applicants assert that oral administration does not include administration to the nasopharynx of the respiratory tract as recited in claim 61. Applicants refer to the attached Exhibit A. Exhibit A indicates oral administration as being enteric administration and that the effect of oral administration is a systemic effect. This is the case with the methods of Stolle et al. The administration taught by Stolle et al. results in a systemic effect. Furthermore, there is no indication that oral administration includes nasal administration and in fact, it is apparent from the disclosure in Exhibit A that nasal administration is different and has different effects (systemic vs. local) than oral administration. In contrast, the present invention relates to coating the nasopharynx of the respiratory tract with adherence inhibiting material and this a topical application and the result is a local effect, not a systemic effect. Coating of the nasopharynx coats the upper airways and prevents penetration and/or colonization by the pathogen of the mucosal barrier in the upper airways and prevents the subsequent infection of the lower airways.

Furthermore, Stolle et al. teaches purification of the antibody from the eggs and it is the purified antibody that is administered to the mammal. See col. 6, lines 50-55 and col. 8, lines 33-35. There is no disclosure that an unpurified egg mixture can be sprayed into an animal's respiratory tract to treat respiratory illnesses as disclosed in the present invention.

Applicants assert that Van Donkersgoed et al. merely relates to vaccination of the beef cows and/or the calves and relates to maternal transfer of *Haemophilus somnus* antibodies to

calves. There is no disclosure related to use of heterologous antibodies from fowl and administering antibodies to the nasopharynx for a local effect to prevent penetration and/or colonization of the upper airways.

Applicants assert that none of the cited art, alone or combined, teach the use of an egg mixture administered to the nasopharynx of the respiratory tract of an animal to decrease the incidence of respiratory illnesses in animals. Based on this discussion, Applicants respectfully request the removal of the rejections over Stolle et al., and Van Donkersgoed et al.

Rejections over Stolle et al. and Van Donkersgoed in view of Emery et al.

The Office Action rejected claims 62, 77 and 80 under 35 U.S.C. 103(a) as being unpatentable over Stolle et al, Van Donkersgoed et al. in view of Emery et al. The Office Action indicated that Stolle et al. and Van Donkersgoed et al., have been discussed above, but neither specifically recite adding preservatives to prevent microbial growth and extend shelf-life.

The Office Action asserted that Emery et al. teach immunizing a bird to provide passive immunity protection against a bacterial pathogen, such as with *Pasteurella multicoda* and *Haemophilus* species and teach that the avian-derived immunoglobulins provides a higher level of specificity and a reduced amount of undesirable side effects as compared to immunoglobulins derived from mammalian serum. The Office Action asserted that Emery et al. teach immunization will stimulate the female bird to produce eggs containing a high level of the immunoglobulin of interest, resulting in eggs being separated and purified and combining the egg resulting product with physiologically acceptable carriers, and other additives. The Office Action indicates that Emery et al. indicate that the composition may be administered orally, parenterally, or by respiratory aerosolization.

The Office Action concluded that it would have been prima facie obvious to one of ordinary skill in the art to incorporate using preservatives as taught by Emery et al., to the method of decreasing respiratory illness in animals by inhibiting the ability of the organisms causing respiratory illness as taught by Stolle et al., and Van Donkersgoed et al., in order to provide more efficient passive immunization results. The Office Action asserted that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Stolle et al., and Van Donkersgoed et al., teach the desire to produce the avian-derived immunoglobulins for pharmaceutical applications in the treatment of respiratory illness wherein

the modification adds preservatives, extends shelf life and is administered by aerolization. The Office Action further asserted that one having ordinary skill in the art would have been motivated to make such a combination because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function, and the combination would have yielded predictable results. The Office Action also indicated that it would have been prima facie obvious to combine the cited art to advantageously decrease respiratory illness in animals and inhibit the ability of respiratory causing organisms.

Applicants assert that the present invention is not obvious over the cited art. Stolle et al. and Van Donkersgoed et al are discussed above. Applicants assert that there is no teaching in Emery et al. related to administration of an egg mixture to the nasopharynx region of the respiratory tract in order to prevent penetration and/or colonization of the mucosal barrier in the upper airways. Applicants assert that Emery et al. generally teaches passive immunization and specifically teaches purification of antibodies obtained from fowl. In Emery et al., all of the administration is of highly purified antibody, not an egg mixture as in the present invention. Applicants assert that the advantages of using the egg mixture include eliminating the high cost of obtaining a highly purified antibody. Furthermore, one of ordinary skill in the art would not expect the use of an egg mixture for coating the respiratory tract would be successful because the desired antibody would not be highly purified and therefore, would not be effective. Applicants' disclosure is the first to show the use of an unpurified egg mixture that is administered to the nasopharynx region and that leads to a decrease in the incidence of respiratory illnesses.

The Office Action indicated that Emery et al. teach a preservative. The use of a preservative is not the inventive feature of the present invention. Applicants assert that independent claim 61 is not obvious over the cited art and the dependent claims 63, 77 and 80 are also not obvious over the cited art.

Based on the discussion above, Applicants respectfully request the removal of the rejections over Stolle et al., and Van Donkersgoed et al. and in view of Emery et al.

Rejections over Stolle et al., Emery et al. and Van Donkersgoed in view of Nash et al.

The Office Action rejected claims 64 under 35 U.S.C. 103(a) as being unpatentable over Stolle et al, Emery et al, and Van Donkersgoed et al., as applied to claims 61-62 and further in

view of Nash et al. The Office Action asserted that Stolle et al, Emery et al, and Van Donkersgoed et al. are as stated above and that Nash et al. teach a microbial adherence inhibitor in the form of fowl egg antibodies and that these can be used in a feeding program and works well with the use of additives such as molasses. The Office Action concluded that it would have been prima facie obvious to one of ordinary skill in the art to incorporate the molasses to the contents of the egg product as taught by Nash et al. to the method of decreasing respiratory illness as taught by Stolle et al, Emery et al, and Van Donkersgoed et al. to better distribute the egg material. The Office Action rejected claim 64 under 35 U.S.C. §103(a) as being unpatentable over Stolle et al., Emery et al., and Van Donkersgoed et al., as applied to claim 61-62 above, and further in view of Nash et al.

The Office Action indicated that Stolle et al., Emery et al. and Van Donkersgoed et al. are as discussed above, but neither specifically recite adding molasses to the contents of the harvested eggs. The Office Action asserted that Nash et al., teach a microbial adherence inhibitor in the form of fowl egg antibodies made by inoculating female birds with the immunogen as described in paragraph 28 of Nash et al. The Office Action further asserted that Nash et al., teach the inhibitor product can be used in almost any kind of feeding program, and works well as feed additives such as molasses and that the antibody microbial inhibitor material may be stored or shipped on carrier materials such as soy bean hulls, boluses and/or tablets.

The Office Action concluded that it would have been prima facie obvious to one of ordinary skill in the art to incorporate adding molasses to the contents of the egg produce as taught by Nash et al., to the method of decreasing animal respiratory illness by inhibiting the ability of the organisms to adhere to mucous membranes, bronchi and alveolar cell as taught by the prior art references in order to better distribute the egg product material in a uniform method to the receiving animals. The Office Action asserted that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention and would have been motivated to make such a combination because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function, and the combination would have yielded predictable results.

Applicants respectfully disagree. Applicants assert that independent claim 61 and dependent claim 62 are patentable over Stolle et al, Emery et al, and Van Donkersgoed et al. for the reasons discussed above. Nash et al does not contribute any teaching to obviate claim 61 and merely discloses the addition of molasses. Applicants assert that claim 61 is patentable over the cited art and dependent claim 64 is also patentable over the cited art.

Applicants respectfully request the removal of the rejections over Stolle et al., Emery et al., and Van Donkersgoed et al. and in view of Nash et al.

Rejections over Stolle et al. and Van Donkersgoed and in view of Weiner et al.

The Office Action rejected claim 63 under 35 U.S.C. § 103(a) as being unpatentable over Stolle et al., and Van Donkersgoed et al., as applied to claim 61 above, and further in view of Weiner et al. (U.S. Patent No. 5,556,744). The Office Action asserted that Stolle et al., and Van Donkersgoed et al., have been discussed above but none specifically recite adding the preservative potassium sorbate. The Office Action indicated that Weiner et al., teach generating peptides useful in vaccine compositions and for generating antibodies for therapeutic compositions by passive immunization and teach adjuvants, preservative, chemical stabilizers including potassium sorbate. The Office Action also indicated that Weiner et al., teach pharmaceutical compositions useful in passive immunization can include the same ingredients, and preservatives as those ingredients known for active immunization.

The Office Action concluded that it would have been prima facie obvious to one of ordinary skill in the art to incorporate the preservative potassium sorbate as taught by Weiner et al., to the method of decreasing respiratory illness as taught by the prior art references in order to act as a preservative within the pharmaceutically acceptable carrier. The Office Action also asserted that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Stolle et al., and Van Donkersgoed et al., teach the product of inhibition material for pharmaceutical applications in the treatment of respiratory illness. The Office Action also alleged that one having ordinary skill in the art would have been motivated to make such a combination because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Applicants respectfully disagree. Applicants assert that independent claim 61 is patentable over Stolle et al, and Van Donkersgoed et al. for the reasons discussed above. Weiner et al does not contribute any teaching to obviate claim 61 and merely discloses the use of potassium sorbate. Applicants assert that independent claim 61 is patentable over the cited art and dependent claim 63 is also patentable over the cited art.

Applicants respectfully request the removal of the rejections over Stolle et al., and Van Donkersgoed et al. and in view of Weiner et al.

Rejections over Stolle et al. and Van Donkersgoed in view of Okuno et al.

The Office Action rejected claim 78 under 35 U.S.C. § 103(a) as being unpatentable over Stolle et al., and Van Donkersgoed et al., as applied to claims 61 and 68 above, and further in view of Okuno et al. (U.S. Patent No. 6,337,070). The Office Action indicated that Stolle et al., and Van Donkersgoed et al., have been discussed above, however neither teach the viruses being swine influenza virus.

The Office Action indicated that Okuno et al., teach inoculation with respiratory viruses comprising swine influenza (H1N1, H3N2) and teach the need for antibodies takes having cross-recognizing ability for influenza virus A virus subparticles and has a virus neutralization activity. The Office Action asserted that it is well known in the art that people get sick from avian-human influenza viruses generated in pigs because pigs have vectors for both avian and human receptors, thus there is a need to prevent interspecies transmission. The Office Action indicates that Okuno et al., teaches the need for safe vaccine.

The Office Action conclude that it would have been prima facie obvious to one of ordinary skill in the art at the time the invention to incorporate inoculation with respiratory swine influenza viruses comprising swine influenza (H1N1, H3N2) as taught by Okuno et al., to the method of Stolle et al., in order to have antibody containing contents that have recognizing ability for influenza virus. The Office Action indicated that one of ordinary skill in the art would have had a reasonable expectation of success and would have been motivated to do this because Stolle et al., and Okuno et al. teach immunization with viral antigens. The Office Action concluded it would have been prima facie obvious to combined the invention of Stolle et al., Van Donkersgoed and Okuno et al., to advantageously achieve a decrease in respiratory illness in animals against infectious swine influenza virus.

Applicants respectfully disagree. Applicants assert that independent claim 61 is patentable over Stolle et al, and Van Donkersgoed et al. for the reasons discussed above. Okuno et al does not contribute any teaching to obviate claim 61 and discloses the need for a safe vaccine against swine influenza viruses. There is no disclosure in Okuno related to the invention as claimed in independent claim 61. Applicants assert that independent claim 61 is patentable over the cited art and dependent claim 63 is also patentable over the cited art.

Applicants respectfully request the removal of the rejections over Stolle et al., and Van Donkersgoed et al. and in view of Okuno et al.

Rejections over 35 U.S.C 112, second paragraph

The Office Action rejected claim 66 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action alleged that claim 66 recites the limitation "the organism mixture" in the claim and that there is insufficient antecedent basis for this limitation in the claim.

Applicants have amended claim 66 to more clearly point out and distinctly claim the subject matter. Applicants assert that claim 66 is now allowable. Applicants request the removal of this rejection based 35 USC 112, second paragraph.

Rejections over 35 U.S.C 112, first paragraph

The Office Action rejected claim 80 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action indicated that the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), a the time the application was filed, had possession of the claimed invention. The Office Action indicated that this is a new matter rejection.

The Office Action asserted that neither the specification nor originally presented claims provides support for a method wherein the birds are separated into different groups, each group of birds inoculated with a different microbial organism of the organism mixture and the egg mixture comprises adherence inhibiting material from all of the groups of birds.

The Office Action asserted that applicant did not point to support in the specification for a method where the birds are separated into different groups, each group of birds inoculated with

different microbial organism of the organism mixture and the egg mixture comprises adherence inhibiting material from all of the groups of birds.

Applicants assert that Example 12 in the Specific discloses this embodiment. In Example 12, each bird or group of birds are inoculated with a different microbial organism. The eggs from these birds are collected and the contents of the eggs, after removal of the shells, were mixed and evaluated. The combined egg mixtures were analyzed for activity against each of the immunogens. Applicants assert that this specific embodiment is claimed in amended claim 80. In addition, Applicants have amended claim 80 to more distinctly claim the subject matter of Example 12.

Based on the above discussion and the claim amendments, Applicants respectfully request the removal of all of the rejections. Applicants assert that all of the claims, as written, are allowable.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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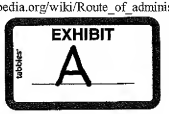

Route of administration

From Wikipedia, the free encyclopedia

A **route of administration** in pharmacology and toxicology is the path by which a drug, fluid, poison, or other substance is taken into the body.[1]

Contents

Classification

Routes of administration are usually classified by application location (or exposition). The route or course the active substance takes from application location to the location where it has its target effect is usually rather a matter of pharmacokinetics (concerning the processes of uptake, distribution, and elimination of drugs). Nevertheless, some routes, especially the transdermal or transmucosal routes, are commonly referred to *routes of administration*. The location of the target effect of active substances are usually rather a matter of pharmacodynamics (concerning e.g. the physiological effects of drugs[2]). Nevertheless, there is also a classification of routes of administration that basically distinguishes whether the effect is local (in "topical" administration) or systemic (in "enteral" or "parenteral" administration).

Application location

Gastrointestinal/enteral

Administration through the gastrointestinal tract is sometimes termed *enteral or enteric administration*

(strictly meaning 'through the intestines'). *Enteral/enteric administration* usually includes *oral*[3] (through the mouth) and *rectal* (into the rectum)[3] administration, in the sense that these are taken up by the intestines. However, uptake of drugs administered orally may also occur already in the stomach, why *gastrointestinal* (along the gastrointestinal tract) may be a more fitting word for this route of administration. Furthermore, some application locations often classified as *enteral*, such as sublingual[3] (under the tongue) and sublabial or buccal (between the cheek and gums/gingiva), are taken up in the proximal part of the gastrointestinal tract without reaching the intestines. Strictly enteral administration (directly into the intestines) can be used for systemic administration, as well as local (sometimes termed topical), such as in enema where e.g. contrast media is infused into the intestines for imaging. However, in the classification system basically distinguishing substances by location of their effects, the term enteral is reserved for substances with systemic effects.

Many drugs as tablets, capsules, or drops are taken orally. Administration methods directly into the stomach include those by gastric feeding tube or gastrostomy. Substances may also be placed into the small intestines, as with a duodenal feeding tube and enteral nutrition.

Central nervous system

- epidural (synonym: peridural) (injection or infusion into the epidural space), e.g. epidural anesthesia
- intracerebral (into the cerebrum) direct injection into the brain. Used in experimental research of chemicals[4] and as a treatment for malignancies of the brain.[5] The intracerebral route can also interrupt the blood brain barrier from holding up against subsequent routes.[6]
- intracerebroventricular (into the cerebral ventricles) administration into the ventricular system of the brain. One use is as a last line of opioid treatment for terminal cancer patients with intractable cancer pain.[7]

Other locations

- epicutaneous (application onto the skin). It can be used both for local effect as in allergy testing and typical local anesthesia, as well as systemic effects when the active substance diffuses through skin in a transdermal route.
- intradermal, (into the skin itself) is used for skin testing some allergens, and also for mantoux test for Tuberculosis
- subcutaneous (under the skin), e.g. insulin, a slang term for this method of administration is skin popping (usually done with recreational drugs)
- nasal administration (through the nose) can be used for topically acting substances, as well as for insufflation of e.g. decongestant nasal sprays to be taken up along the respiratory tract. Such substances are also called *inhalational*, e.g. inhalational anesthetics.
- intravenous (into a vein), e.g. many drugs, total parenteral nutrition
- intraarterial (into an artery), e.g. vasodilator drugs in the treatment of vasospasm and thrombolytic drugs for treatment of embolism
- intramuscular (into a muscle), e.g. many vaccines, antibiotics, and long-term psychoactive agents. Recreationally the colloquial term 'muscling' is used.[8]
- intracardiac (into the heart), e.g. adrenaline during cardiopulmonary resuscitation (no longer commonly performed)
- intraosseous infusion (into the bone marrow) is, in effect, an indirect intravenous access because the bone marrow drains directly into the venous system. This route is occasionally used for drugs and

fluids in emergency medicine and pediatrics when intravenous access is difficult.
- intrathecal (into the spinal canal) is most commonly used for spinal anesthesia and chemotherapy
- intraperitoneal, (infusion or injection into the peritoneum) e.g. peritoneal dialysis
- Intravesical infusion is into the urinary bladder.
- intravitreal, through the eye
- Intracavernous injection, an injection into the base of the penis
- Intravaginal, e.g. topical estrogens, antibacterials
- Intrauterine
  - Extra-amniotic administration, between the endometrium and fetal membranes

Route from application to target

The route or course the active substance takes from application location to the location where it has its target effect is usually rather a matter of pharmacokinetics (concerning the processes of uptake, distribution, and elimination of drugs). Nevertheless, the following routes are commonly referred to as *routes of administration*:

- transdermal (diffusion through the intact skin for systemic rather than topical distribution), e.g. transdermal patches such as fentanyl in pain therapy, nicotine patches for treatment of addiction and nitroglycerine for treatment of angina pectoris.
- transmucosal (diffusion through a mucous membrane), e.g. insufflation (snorting) of cocaine, sublingual, i.e. under the tongue, sublabial, i.e. between the lips and gingiva, nitroglycerine, vaginal suppositories

Local or systemic effect

Routes of administration can also basically be classified whether the effect is local (in topical administration) or systemic (in enteral or parenteral administration):

- *topical*: local effect, substance is applied directly where its action is desired.[9] Sometimes, however, the term *topical* is defined as applied to a localized area of the body or to the surface of a body part,[10] without necessarily involving target effect of the substance, making the classification rather a variant of the classification based on application location.
- *enteral*: desired effect is systemic (non-local), substance is given via the digestive tract.
- *parenteral*: desired effect is systemic, substance is given by routes other than the digestive tract.

Topical

- epicutaneous (application onto the skin), e.g. allergy testing, typical local anesthesia
- inhalational, e.g. asthma medications
- enema, e.g. contrast media for imaging of the bowel
- eye drops (onto the conjunctiva), e.g. antibiotics for conjunctivitis
- ear drops - such as antibiotics and corticosteroids for otitis externa
- through mucous membranes in the body

Enteral

In this classification system, enteral administration is administration that involves any part of the

gastrointestinal tract and has systemic effects:

- by mouth (orally), many drugs as tablets, capsules, or drops
- by gastric feeding tube, duodenal feeding tube, or gastrostomy, many drugs and enteral nutrition
- rectally, various drugs in suppository

Parenteral

- intravenous (into a vein), e.g. many drugs, total parenteral nutrition
- intra-arterial (into an artery), e.g. vasodilator drugs in the treatment of vasospasm and thrombolytic drugs for treatment of embolism
- intraosseous infusion (into the bone marrow) is, in effect, an indirect intravenous access because the bone marrow drains directly into the venous system. This route is occasionally used for drugs and fluids in emergency medicine and pediatrics when intravenous access is difficult.
- intra-muscular

Advantages and disadvantages

There are advantages and disadvantages to each route of administration

Inhalation

Advantages

- Fastest method, 7–10 seconds for the drug to reach the brain
- User can titrate (regulate the amount of drug they are receiving)

Disadvantages

- Typically a more addictive route of administration because it is the fastest, leading to instant gratification. In addition, drugs taken by inhalation do not stay in the bloodstream for as long, causing the user to redose more quickly and intensifying the association between consuming the drug and its effects.
- Difficulties in regulating the exact amount of dosage
- Patient having difficulties administering a drug via inhaler

Injection

Injection encompasses intravenous (IV), intramuscular (IM), and subcutaneous (subcut) [11]

Advantages

- Fast: 15–30 seconds for IV, 3–5 minutes for IM and subcutaneous (subcut)
- 100% bioavailability
- suitable for drugs not absorbed by the gut or those that are too irritant (anti-cancer)
- One injection can be formulated to last days or even months, e.g., Depo-Provera, a birth control shot that works for three months
- IV can deliver continuous medication, e.g., morphine for patients in continuous pain, or saline drip

for people needing fluids

Disadvantages

- Onset of action is quick, hence more risk of addiction when it comes to injecting drugs of abuse
- Patients are not typically able to self-administer
- Belonephobia, the fear of needles and injection.
- If needles are shared, there is risk of HIV and other infectious diseases
- It is the most dangerous route of administration because it bypasses most of the body's natural defenses, exposing the user to health problems such as hepatitis, abscesses, infections, and undissolved particles or additives/contaminants
- If not done properly, potentially fatal air boluses (bubbles) can occur.
- Need for strict asepsis

Uses

- Some routes can be used for topical as well as systemic purposes, depending on the circumstances. For example, inhalation of asthma drugs is targeted at the airways (topical effect), whereas inhalation of volatile anesthetics is targeted at the brain (systemic effect).

- On the other hand, identical drugs can produce different results depending on the route of administration. For example, some drugs are not significantly absorbed into the bloodstream from the gastrointestinal tract and their action after enteral administration is therefore different from that after parenteral administration. This can be illustrated by the action of naloxone (Narcan), an antagonist of opiates such as morphine. Naloxone counteracts opiate action in the central nervous system when given intravenously and is therefore used in the treatment of opiate overdose. The same drug, when swallowed, acts exclusively on the bowels; it is here used to treat constipation under opiate pain therapy and does not affect the pain-reducing effect of the opiate.

- Enteral routes are generally the most convenient for the patient, as no punctures or sterile procedures are necessary. Enteral medications are therefore often preferred in the treatment of chronic disease. However, some drugs can not be used enterally because their absorption in the digestive tract is low or unpredictable. Transdermal administration is a comfortable alternative; there are, however, only a few drug preparations that are suitable for transdermal administration.

- In acute situations, in emergency medicine and intensive care medicine, drugs are most often given intravenously. This is the most reliable route, as in acutely ill patients the absorption of substances from the tissues and from the digestive tract can often be unpredictable due to altered blood flow or bowel motility.

See also

- ADME
- Catheter
- Dosage form
- Drug injection
- Hypodermic needle
- Medical injection
- Intravenous Marijuana Syndrome

- List of medical inhalants

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External links

- The 10th US-Japan Symposium on Drug Delivery Systems (http://www.drug-delivery-systems.org)
- FDA Center for Drug Evaluation and Research Data Standards Manual: Route of Administration. (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071667.htm)
- FDA Center for Drug Evaluation and Research Data Standards Manual: Dosage Form. (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071666.htm)
- A.S.P.E.N. American Society for Parenteral and Enteral Nutrition (http://www.nutritioncare.org/)

- MeSH *Drug+Administration+Routes (http://www.nlm.nih.gov/cgi/mesh/2011/MB_cgi?mode=&term=Drug+Administration+Routes)*

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